

Charles M. Lizza
William C. Baton
SAUL EWING LLP
One Riverfront Plaza, Suite 1520
Newark, NJ 07102
(973) 286-6700

CL

*Attorneys for Plaintiffs
Sumitomo Dainippon Pharma Co., Ltd.
and Sunovion Pharmaceuticals Inc.*

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

SUMITOMO DAINIPPON PHARMA
CO., LTD. and SUNOVION
PHARMACEUTICALS INC.,

Plaintiffs,

v.

INVAGEN PHARMACEUTICALS,
INC.,

Defendant.

**Civil Action No. 15-280 (SRC)(CLW)
Civil Action No. 15-281 (SRC)(CLW)
(consolidated)**

(Filed Electronically)

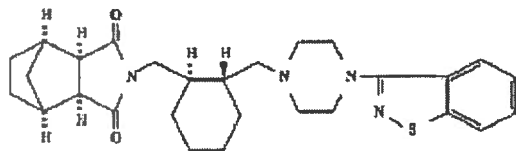
FINAL JUDGMENT AND ORDER OF PERMANENT INJUNCTION

WHEREAS, Defendant InvaGen Pharmaceuticals, Inc. ("InvaGen") submitted Abbreviated New Drug Application No. 208028 ("InvaGen's ANDA") seeking approval to engage in the commercial manufacture, use, sale, and/or offer for sale within the United States, and/or importation into the United States of generic lurasidone hydrochloride tablets 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg for treatment of

schizophrenia and depressive episodes associated with Bipolar I Disorder (bipolar depression), as monotherapy and as adjunctive therapy with lithium or valproate (collectively, “InvaGen’s ANDA Products”) prior to the expiration of U.S. Patent No. 5,532,372 (“the ’372 patent”);

WHEREAS, Plaintiffs Sumitomo Dainippon Pharma Co., Ltd. and Sunovion Pharmaceuticals Inc. (collectively, “Sunovion”) brought Civil Action No. 15-281 against InvaGen, alleging, among other things, that the submission of InvaGen’s ANDA and InvaGen’s ANDA Products infringe Claim 14 of the ’372 patent;

WHEREAS, on November 15, 2016, this Court issued an Opinion and Order construing the following term of Claim 14: “[t]he imide compound of the formula:



,” as “lurasidone, lurasidone’s enantiomer, as well as mixtures of these enantiomers” (“the *Markman* Decision”) [D.I. 106];

WHEREAS, InvaGen has agreed to stipulate that, under the Court’s construction in the *Markman* Decision, the submission of InvaGen’s ANDA to the United States Food and Drug Administration (“FDA”) for the purpose of obtaining regulatory approval to engage in the commercial manufacture, use, sale, and/or offer for sale within the United States, and/or importation into the United States of InvaGen’s ANDA Products before the

expiration of the '372 patent was an act of infringement of Claim 14 of the '372 patent under 35 U.S.C. § 271(e)(2)(A);

WHEREAS, Sunovion and InvaGen have agreed to enter into a final judgment of the above-captioned action; and

WHEREAS, Sunovion and InvaGen have agreed to stipulate that Claim 14 of the '372 patent is valid and enforceable, and InvaGen has further agreed that it will not, whether directly or indirectly, challenge the patentability, validity, or enforceability of the '372 patent in this or any other action.

The Court, upon the stipulation and request of Sunovion and InvaGen, and for good cause shown, issues the following Final Judgment and Order of Permanent Injunction.

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED THAT:

1. Sunovion and InvaGen do not contest personal jurisdiction in the United States District Court for the District of New Jersey for the purposes of the above-captioned action only.
2. This Court retains exclusive jurisdiction to enforce or supervise performance under this Final Judgment and Order of Permanent Injunction.
3. InvaGen concedes that Claim 14 of the '372 patent is valid and enforceable.

4. Judgment is entered in favor of Sunovion and against InvaGen on InvaGen's counterclaim that Claim 14 of the '372 patent is invalid.

5. InvaGen and its Affiliates shall not, directly or indirectly: (a) challenge the patentability, validity, or enforceability of the '372 patent; and/or (b) assist, encourage, support, finance, or otherwise provide any information to, any third party for the purpose of challenging the patentability, validity, and/or enforceability of, and/or asserting noninfringement of the '372 patent.¹ Such challenges to the patentability, validity, or enforceability of the '372 patent include, but are not limited to, filing or maintaining (1) a request for *inter partes* review; (2) a request for reexamination; (3) any other pre- or post-grant proceeding in the United States Patent and Trademark Office; and (4) a declaratory judgment action.

6. InvaGen stipulates that, under the Court's construction in the *Markman* Decision, the submission of InvaGen's ANDA to the FDA for the purpose of obtaining regulatory approval to engage in the commercial manufacture, use, sale, and/or offer for sale within the United States, and/or importation into the United States of InvaGen's

¹ For purposes of this Final Judgment and Order of Permanent Injunction, the term "Affiliate" shall mean any entity controlling, controlled by, or under common control with InvaGen, but only as long as such control continues, where "control" means: (1) ownership of at least fifty percent (50%) of the equity or beneficial interest of such entity, or the right to vote for and/or appoint a majority of the board of directors or other governing body of such entity; and/or (2) the power to directly or indirectly direct or cause the direction of the management and policies of such entity by any means whatsoever.

ANDA Products before the expiration of the '372 patent was an act of infringement of Claim 14 of the '372 patent under 35 U.S.C. § 271(e)(2)(A).

7. Judgment of infringement of Claim 14 of the '372 patent is hereby entered in favor of Sunovion and against InvaGen on InvaGen's counterclaim that Claim 14 is not infringed.

8. Nothing herein shall be deemed to be an admission, acceptance, or adoption by InvaGen of the claim construction set forth in the *Markman* Decision.

9. Nothing herein shall preclude InvaGen from pursuing an appeal of the claim construction set forth in the *Markman* Decision upon entry of this Final Judgment and Order of Permanent Injunction.

10. It is further stipulated and ordered that with the exception of paragraphs 3-5, InvaGen does not waive any rights to seek modification of any portion of this Final Judgment, including the injunctive relief granted, to the extent the Court's claim construction is modified on appeal. Sunovion does not waive any rights to oppose any such request by InvaGen.

11. In accordance with 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of InvaGen's ANDA No. 208028 shall be no earlier than January 2, 2019, the date of the expiration of the '372 patent, including any patent term extension and/or adjustment, and the expiration of pediatric exclusivity under 21 U.S.C. § 355a awarded to Sunovion. If Sunovion becomes entitled to any other exclusivities or patent term

extension and/or adjustment that are not referenced herein, Sunovion and/or InvaGen may apply to the Court for further relief as may be appropriate.

12. In accordance with 35 U.S.C. § 271(e)(4)(B), InvaGen and its Affiliates, successors, partners, employees, agents, attorneys, and all those acting in privity or concert with them, and who have received actual notice of this injunction by personal service or otherwise, are hereby restrained and enjoined from engaging in the commercial manufacture, use, sale, offer for sale, and/or distribution within the United States, and/or importation into the United States of any lurasidone product that is the subject of InvaGen's ANDA No. 208028 through and until January 2, 2019, the expiration of the '372 patent, including any patent term extension and/or adjustment, and the expiration of pediatric exclusivity under 21 U.S.C. § 355a awarded to Sunovion. If Sunovion becomes entitled to any other exclusivities or patent term extension and/or adjustment that are not referenced herein, Sunovion and/or InvaGen may apply to the Court for further relief as may be appropriate.

13. Nothing herein shall be deemed an admission of validity, enforceability or infringement of any claim other than Claim 14 of the '372 patent, or any other patent not asserted in the above-captioned action.

14. Except as provided herein, all remaining claims and counterclaims as well as all pending motions between Sunovion and InvaGen are dismissed or denied without prejudice as moot, but may be reinstated at the request of the moving party should the case be remanded to this Court for further proceedings.

IT IS HEREBY STIPULATED:

Dated: February 24, 2017

By: s/ William C. Baton
Charles M. Lizza
William C. Baton
SAUL EWING LLP
One Riverfront Plaza, Suite 1520
Newark, NJ 07102-5426
(973) 286-6700

By: s/ Salvatore Guerriero
Salvatore Guerriero
Robert Silver (*Pro Hac Vice*)
CAESAR RIVISE, PC
1635 Market Street
12th Floor – Seven Penn Ctr.
Philadelphia, PA 19103-2212

Of Counsel:

Joseph M. O'Malley, Jr.
Preston K. Ratliff II
Bruce M. Wexler
PAUL HASTINGS LLP
200 Park Avenue
New York, NY 10166
(212) 318-6000

*Attorneys for Defendant
InvaGen Pharmaceuticals, Inc.*

*Attorneys for Plaintiffs
Sumitomo Dainippon Pharma Co., Ltd.
and Sunovion Pharmaceuticals Inc.*

IT IS SO ORDERED, this 28 day of Feb, 2017


Hon. Stanley R. Chesler, U.S.D.J.